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Indian Standard

SPECIFICATION FOR SIGMOIDOSCOPE

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Corrigendum

(*Page 8, clause 6.3, line 2*) - Delete the words 'pumping action'.

(EDC 36)

Reprography Unit, ISI, New Delhi

IS : 5750 - 1970

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SPECIFICATION FOR SIGMOIDOSCOPE

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Indian Standard

SPECIFICATION FOR SIGMOIDOSCOPE

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 25 August 1970, after the draft finalized by the Optical and Mathematical Instruments Sectional Committee had been approved by the Mechanical Engineering Division Council.

0.2 Sigmoidoscope is a diagnostic medical instrument used for the visual examination of the sigmoid colon of large intestine. It is essentially a cylindrical tube with a nipple for (double bellow) insufflator. It carries a light carrier for illumination and window assembly for observation purpose. It is also supplied with an obturator to facilitate insertion of the instrument into the human body.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers the general and functional requirements of sigmoidoscope. A typical sigmoidoscope is shown in Fig. 1.

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions shall apply.

2.1 Obturator — It is a device to be put inside the main tube and consists of a rod with a plunger at one end and a handle at the other end.

2.2 Double Bellow Insufflator — It is a device for controlled supply of air inside the main tube.

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*Rules for rounding off numerical values (*revised*).

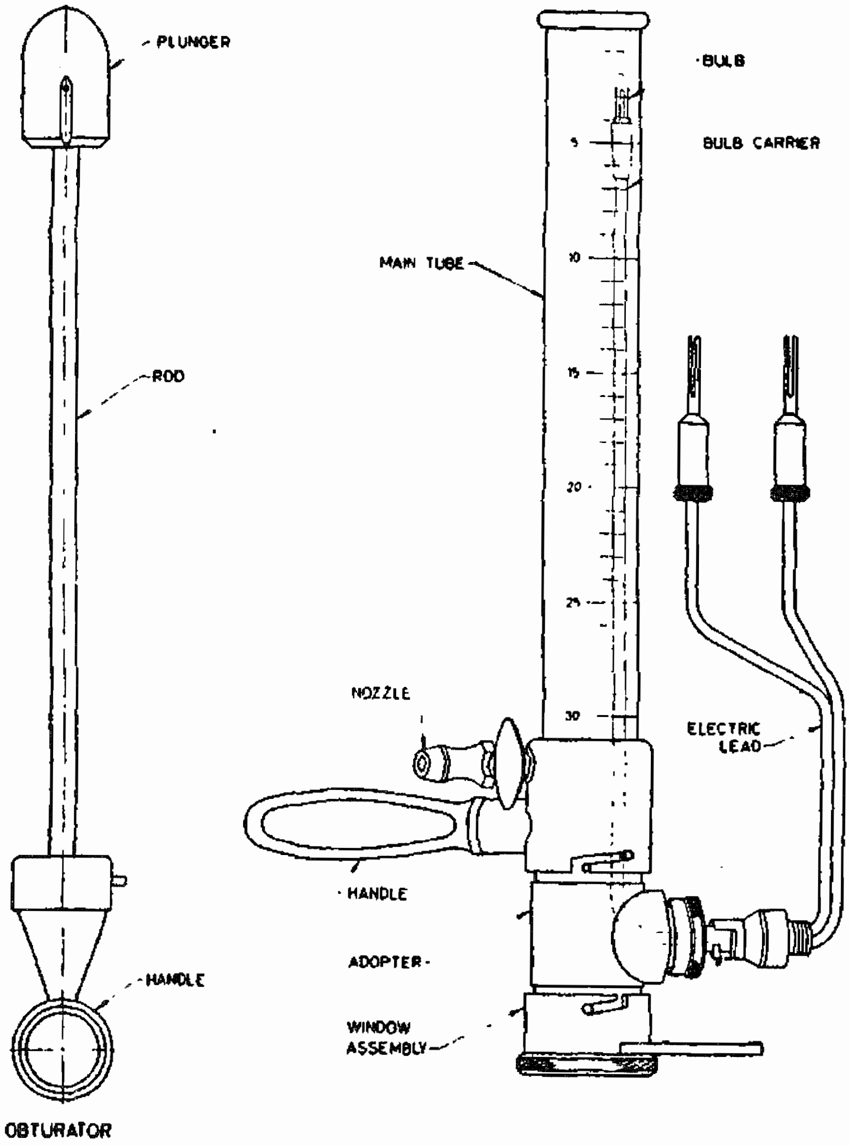

Fig. 1 NOMENCLATURE oF SIGMOIDOSCOPE

3. GENERAL REQUIREMENTS

3.1 Each part of the sigmoidoscope shall be made from material of suitable strength and shall be suitably finished.

3.2 All metal parts other than stainless steel shall be nickel chromium plated or shall be given any suitable finish. Nickel-chromium plating shall conform to IS : 1068-1968* or IS : 4827-1968†.

3.3 Plating on each part shall be durable to resist wear and corrosion.

3.4 Fitting of components shall be proper and there shall be no play between the mating components.

3.5 The dimensions of the threaded and push fit portions shall be such as to ensure interchangeability of spare parts.

3.6 All sharp edges shall be rounded off.

3.7 The case for the instrument shall be made of well-seasoned wood or any suitable material. The case shall be able to accommodate all the sub-assemblies and accessories of the instrument. It shall be so designed that when the instrument and accessories are kept in position and the lid closed, there shall be no rattling inside the case.

4. FUNCTIONAL REQUIREMENTS

4.0 The essential parts of the instrument shall meet the following requirements.

4.1 Main Tube

4.1.1 The tube shall be 33 cm long. The external diameter of the insertion part of the main tube shall be $20.3\pm^{+0}_{-0.1}$ mm. The main tube shall be graduated to a length of 30 cm starting from the insertion end.

4.1.2 The scale shall be sub-divided into one centimetre markings and figured at every 5 cm.

4.1.3 The handle shall provide a good grip so that the tube may be held in hand conveniently.

4.2 Obturator — When the obturator is fitted on to the main tube, the plunger shall not be rattle inside the main tube and shall snugly cover the entire lumen of the main tube.

4.3 Lamp Holder Assembly

4.3.1 The tapers on both sides of the adapter shall be such that when locked on to the main tube and the window assembly, there shall not be any leakage.

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*Specification for electroplated coatings of nickel and cluomium on iron and steel (*first revision*).

†Specification for electroplated coatings of nickel and cluomium on copper and copper alloys

4.3.2 One end of the plug shall be provided with an attachment for connection to the power supply whereas the other end shall be able to take up a lamp holder.

4.4 Window Assembly

4.4.1 The female taper on window assembly shall be such that when locked on to the lamp holder assembly there shall not be any leakage.

4.4.2 The glass window shall be free from scratches, strains and lensatic errors.

4.5 Lamp

4.5.1 The sigmoidoscope shall be provided with a 3.5V/0.5A lamp of special shape and size. The filament of the lamp shall be coiled type.

4.5.2 The light shall be bright white and shall not be yellowish.

4.5.3 The tip of the glass shall be smooth and of uniform thickness.

4.5.4 The life of the lamp shall be 20 hours when continuously burnt.

4.5.5 The light output of the lamp shall not be less than 1.7 lumens per watt.

4.6 Plug Holder Assembly

4.6.1 The socket, when fitted on to the plug of the lamp holder assembly, shall not have any play.

4.6.2 The connecting pins when inserted into the socket of the power supply unit shall be tight.

4.7 Double Bellow Insufflator

4.7.1 The insufflator (*see* Fig. 2) shall be made of good quality natural tubber or any other suitable material.

4.7.2 The rubber bladder shall be covered with a net made of cotton or any other suitable material to protect it from bursting.

4.7.3 The valves shall be such that sufficient air pressure may be maintained inside the main tube.

4.8 The instrument shall be capable of withstanding sterilization.

5. SPARES

5.1 The sigmoidoscope shall be provided with four lamps specified in **4.5.1**.

6. TESTS

6.1 General — The sigmoidoscope shall initially be examined for the following external defects:

a) Loose, missing or damaged screws/components;

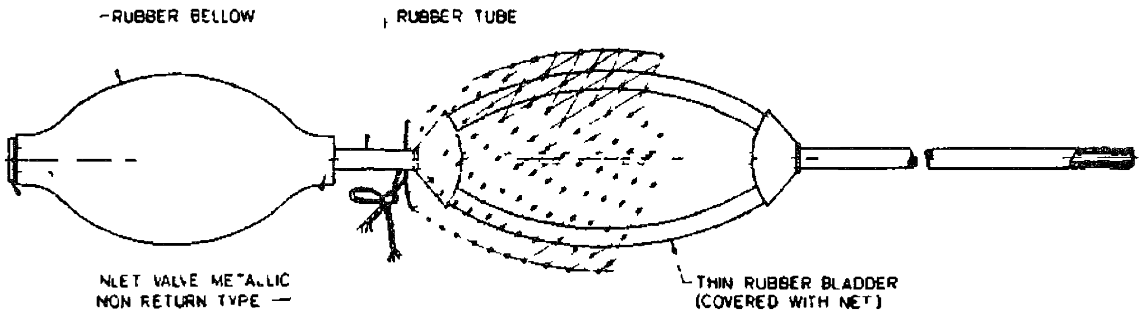

FIG. 2 DOUBLE BELLOW INSUFFLATOR

b) Damage to various sub-assemblies and accessories; and

c) Damage to external finish.

6.2 Glass Window — Slight jerk shall be given to the glass window and it shall be examined that it is not displaced.

6.3 Rubber Insufflator — The insufflator shall be subjected to pumping action 50 times. It shall not show any surface cracks pumping action or other deterioration.

6.4 Air-Tightness — Air-tightness shall be tested as follows:

> After fixing the lamp holder and the window assembly, the opening of the main tube shall be closed and air shall be pumped in with the insufflator while the instrument shall completely be immersed under water. The joints at the plug, between the main tube and the adapter and between the adapter and window assembly, shall be sufficiently air-tight so as to retain the built up pressure inside. However, leakage to the extent of 0.5 cc per minute when subjected to 45 cm water pressure, shall not be objectionable.

6.5 Lamp Life Test — The lamp shall be continuously burnt for 20 hours and there shall be no damage to the lamp.

6.6 Light Output — The light output of the lamp shall be measured by a suitable photometer. The value shall not be less then 1.7 lumens per watt.

7. MARKING

7.1 The sigmoidoscope shall be marked at a suitable place with the manufacturer's name or trade-mark and the serial number. If required by the purchaser, the instrument may also be marked with the year of manufacture.

7.1.1 The sigmoidoscope may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

8. PACKING

8.1 The sigmoidoscope with its spares shall be suitably packed in its case.

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